K112249 #1/2 OCT 25 2011

DePuy Mitek Inc. a Johnson & Johnson company — never stop moving

PRODUCT: HEALIX KNOTLESS™ ANCHOR
SUBMISSION DATE: AUGUST 05TH, 2011
SUBMISSION TYPE: TRADITIONAL

ATTACHMENT 1

510(k) SUMMARY - Healix Knotless™ Anchor

SUBMITTER'S NAME AND ADDRESS

DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

CONTACT PERSON

Deep Pal
Senior Regulatory Affairs Specialist

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DATE PREPARED	August 05th, 2011

NAME OF MEDICAL DEVICE

COMMON/USUAL NAME
Suture Anchor

TRADE NAME/PROPRIETARY NAME
Healix Knotless™ Anchor

SUBSTANTIAL EQUIVALENCE

The proposed Healix Knotless™ Anchor is substantially equivalent to the following devices.

- K061863 — Arthrex PushLock Anchors
- K073412 — DePuy Mitek's Gryphon BR Anchor
- K032717, K060830 and K103831 — Milagro Interference Screws

FDA PRODUCT CODE

MAI, HWC

DEVICE CLASSIFICATION

These types of **Interference Screws** were originally classified as a **Class II** medical device by the **Orthopedic Review Panel,** regulated as 21 CFR 888.3030.

FDA PRODUCT CODE: MAI, HWC
COMMON CLASSIFICATION NAME: Fastener, fixation, biodegradable, soft tissue

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ATTACHMENT 1

Continues...

510(k) SUMMARY - Healix Knotless™ Anchor

DEVICE DESCRIPTION

The proposed Healix Knotless™ Anchor is a once piece implantable cannulated, threaded anchor designed to secure soft tissue to bone. The anchor is provided loaded on a disposable inserter driver device. The proposed anchor is offered in one size. The proposed Healix Knotless™ Anchor is molded with absorbable absorbable Poly *(lactide-co-glycolide)* polymer and Tricalcium Phosphate (TCP).

The proposed Healix Knotless™ Anchor will be provided in one size with outer diameter of 4.75mm.

INDICATIONS FOR USE

The Healix Knotless™ Anchor is indicated for use in the following procedures for reattachment of soft tissue to bone:

Shoulder

- Rotator Cuff
- Biceps Tenodesis

TECHNOLOGICAL CHARACTERSTICS

- The technological characteristics in terms of product design and performance specification; the proposed Healix Knotless™ Anchor is substantially equivalent to the predicate Arthrex PushLock Anchor (K061863) except that the proposed Healix Knotless™ Anchor is smaller in length with a different thread profile and has a slot on one side of the anchor wall (Proximal End).
- The technological characteristics as it relate to the product material specifications, packaging, indications for use and sterilization method; the proposed Healix Knotless™ Anchor is substantially equivalent to the predicate DePuy Mitek's Gryphon BR Anchor (K073412).
  The same absorbable Poly (lactide-co-glycolide) polymer and Tricalcium Phosphate (TCP) material is used to manufacture both the predicate (Gryphon BR) and the proposed Healix Knotless™ Anchor.

NONCLINICAL TESTING

Product Design Verification activities, such as, Insertion Torque, Anchor Pullout (at T=0, 6 and 12 week in-vitro physiological aging), and Torque to Failure were performed on the implant.

SAFETY AND PERFORMANCE

Results of performance and safety testing have demonstrated that the proposed device is substantially equivalent to the predicate device.

Based on the indications for use, technological characteristics, and comparison to predicate devices, the proposed Healix Knotless™ Anchor has been shown to be substantially equivalent to predicate device under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Mitek, Inc
a Johnson & Johnson Company
% Deep Pal
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

OCT 25 2011

Re: K112249
Trade/Device Name: Healix Knotless™ Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI, HWC
Dated: August 5, 2011
Received: August 5, 2011

Dear Deep Pal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112249 (1/1)

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SUBMISSION DATE: AUGUST 05TH, 2011
SUBMISSION TYPE: TRADITIONAL

ATTACHMENT 2

INDICATIONS FOR USE

510(k) Number (if known): K112249

Device Names: Healix Knotless™ Anchor

Indications for Use: The Healix Knotless™ Anchor is indicated for use in the following procedures for reattachment of soft tissue to bone:

Shoulder
- Rotator Cuff
- Biceps Tenodesis

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael Chen for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112249